

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
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Lars WINTHER, et al.)	Group Art Unit: 1641
)	
Application No.: 10/563,820)	Examiner: Christine E. FOSTER
)	
Filed: January 6, 2006)	
)	Confirmation No.: 3909
For: REFERENCE STANDARD FOR)	
DIAGNOSTIC APPLICATIONS (as)	
amended))	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT UNDER PCT RULE 13.1

Applicant now replies to the Restriction Requirement dated July 1, 2008. This reply is accompanied by a petition for a three-month extension of time and fee payment, extending the period of response to November 1, 2008.

In the Restriction Requirement, the Examiner required restriction under 35 U.S.C. § 121 and § 372 between:

Group I - Claims 88¹-104, drawn to a reference standard.

Group II - Claims 105-107, drawn to a kit.

Group III - Claims 108-110, drawn to a method of comparing the amount of a detectable entity with the amount of a reference standard.

¹ Page 2 of the Office Action indicates that Group I consists of claims 1-104. Applicant notes that claims 1-87 were canceled in the Preliminary Amendment filed January 6, 2006. Accordingly, Applicant assumes that Group I consists of claims 88-104.

Group IV - Claims 111-114, drawn to a method of assessing the effectiveness of a procedure.

Group V - Claim 115, drawn to a modified cell.

Group VI - Claim 116, drawn to a method of establishing a cellular distribution of detectable entity in a reference standard.

Applicant provisionally elects to prosecute Group I, claims 88-104, with traverse.

According to PCT Rule 13.2, unity of invention exists when the shared technical feature among the claims defines a contribution of the claimed invention over the prior art. See M.P.E.P. § 1850, 8th Ed. August 2007 Rev. Applicant submits that according to this standard, claims 88-116 should be examined together.

The Office asserts that the “technical feature of Group I is that of a reference standard for a detectable entity comprising (a) a support medium and (b) a compact particle comprising a quantity of detectable entity attached to the compact particle and supported by the medium” and that the “technical feature linking the inventions appears to be that of the compact particle (b).” (Office Action at pp. 2-3.) The Office contends that the rotavirus-like particles containing GFP molecules (“GFP-VLPs”) disclosed in Dundr M. et al., “Quantitation of GFP-Fusion Proteins in Single Living Cells,” J Struct Biol. 140:92-99 (2002) (“*Dundr*”) define “particles that would be considered ‘compact’” and “comprise a quantity of attached detectable entity.” (*Id.* at p. 3.) The Office concludes that “the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.” (*Id.*) Applicant respectfully disagrees.

For example, the Office’s analysis of the technical features of the invention fails to consider the inventive contribution of the support medium element, which links

Groups I-VI. Claims 88, 108, and 116, from which claims 89-107 and 109-114² depend, recite "a support medium" that supports a "compact particle comprising a quantity of detectable entity attached to the compact particle." See, e.g., claim 88. In contrast, the GFP-VLPs disclosed in *Dundr* are used in solution and are not supported by a support medium, as required by the currently pending claims. Thus, *Dundr* neither teaches nor suggests the technical feature of the "support medium" of the instantly claimed invention. Accordingly, the support medium element of the invention is a technical feature shared by Groups I-VI that defines a contribution of the claimed invention over the prior art.

Moreover, for a restriction requirement to be proper under U.S. Patent Law, two criteria must be met: first, the inventions must be independent or distinct as claimed, and second, there must be a serious search burden on the examiner. M.P.E.P. § 803. "If the search and examination of all the claims in an application can be made without serious burden, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions." *Id.* (emphasis added). In this case, the Office has failed to demonstrate that searching Groups I-VI together would impose a serious burden on the Examiner.

Applicant submits that the search of Groups I-VI can be made without undue burden because a literature search for these groups would be largely coextensive, since the same search terms would be used to search the prior art. Specifically, a thorough search for the reference standard of Group I will use the same terms as a search for the methods and kits of Groups II-IV and VI because the reference standard of Group I is

² Applicant acknowledges that claim 115 does not recite "a support medium." However, claim 115 recites "[a] modified cell comprising a detectable entity" Thus, the GFP-VLPs disclosed in *Dundr* are irrelevant to the unity of invention analysis with respect to claim 115.

used in the methods and kits of Groups II-IV and VI. Further, the modified cell of Group V comprises several technical features in common with the reference standard of Group I and can be used in the method of Group VI. Moreover, independent claims 88, 108, 115, and 116 all include common key words and terminology. Hence, key words may be chosen that incorporate the inventions in all of the claim groups without serious burden. Moreover, examining these groups separately would impose extra costs and delays on the Office due to the duplicative search and examination that would be involved. Accordingly, Applicant respectfully submits that examining all the claims of Groups I-VI together would not impose a serious burden on the Examiner.

For at least these reasons, Applicant respectfully requests that the restriction requirement be withdrawn and that all of claims 88-116 be examined together.

Once the elected product claims of Group I are found allowable over the art, Applicant notes that the Office agrees to rejoin the process claims of Groups III and IV that depend from or otherwise require all the limitations of the allowable product claims, in accordance with the Office's policies set forth in M.P.E.P. § 821.04. (See the Office Action at Item 5.)

The Examiner has also required the following species election under PCT Rule 13.1 if Applicant elects any of Groups I-IV:

Compact particle (elect one of the following):

- i. Cell (see claims 90 and 101)
- ii. Cellular organelle (see claim 91)
- iii. Microbead (see claim 94)
- iv. Micelle (see claim 94).

Applicant provisionally elects to prosecute cells (Group i) as the compact particle, with traverse. All of claims 88-90, 92, and 95-104 read on the elected invention.

Applicant respectfully submits that the Office has not shown that a search of the underlying genus would be a serious burden, especially since the same search terms would be used to search the prior art. For instance, a thorough search for the reference standard of Group I will necessarily involve a search for the compact particle embodiments recited in the currently pending claims. Indeed, it is very unlikely that the key words used in such searches would be so narrowly tailored so as to pull up results that distinguish between cells, cellular organelles, and micelles. Accordingly, Applicant respectfully submits that examining all the species together would not impose a serious burden and requests that the species election be withdrawn.

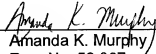
Once the elected species are found allowable over the art, Applicant notes that the Office agrees to extend examination to the unelected species to the extent necessary to find the generic claims allowable, in accordance with 37 C.F.R. § 1.141. (See the Office Action at page 4, middle complete paragraphs.)

This response is accompanied by a petition for a three-month extension of time and appropriate fee payment. Please grant any extensions of time required to enter this response and charge any required fees not found herewith to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 28, 2008

By: 
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